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Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

JUL 18 2005

Office of Regulatory Policy HFD - 13 5600 Fishers Lane, Rockville, MD 20857

Attention: Claudia Grillo

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,937,078. The application was filed on June 7, 2004, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571)272-7744 (telephone) or (571)273-7744 (facsimile).

Karin Ferriter

Senior Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc:

Paul E. Dietze

Morgan, Lewis & Bockius, LLP 1111 Pennsylvania Ave., NW Washington DC 20004

RE: Surpass® (diclofenac sodium) Docket No. 04E-0389